

#26

DAD/H

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Susan Buis

Type or print name of person signing certification

Susan Buis April 2, 2003

Signature

Date

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,690,951

Patentees : David B. Anderson, et al. Attn: Box Patent Ext.

Assignee : Eli Lilly and Company

Issue Date : September 1, 1987

Docket No. : X-5683B

LETTER OF TRANSMITTAL OF AMENDMENT AND SUPPLEMENT TO APPLICATION
FOR EXTENSION OF PATENT TERM

Assistant Commissioner for Patents

Arlington, VA 22202

Sir:

Transmitted herewith for filing is a supplement to an application for extension of term of U.S. Patent No. 4,690,951 and a duplicate thereof, certified as such.

The original Application for Extension of Patent Term was filed February 18, 2000. Upon further review of the Request for Extension of Patent Term, on or about March 28, 2003, amendments and supplementation were necessary and are addressed by the enclosed Amendment and Supplement.

Please charge the filing fee of \$1,120 to deposit account No. 05-0840 in the name of Eli Lilly and Company. An original and two copies of this paper are enclosed. The Assistant Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to account No. 05-0840.

The Amendment and Supplement to application for extension transmitted herewith has been executed by the undersigned agent of the owner of record of the subject patent.

04/09/2003 SLUANG1 00000023 050840 4690951

01 FC:1457 1120.00 CH

ELI LILLY AND COMPANY

By: John C. Demeter
 John C. Demeter
 Attorney for Applicants
 Registration No. 30,167
 Phone: 317-276-3785

Eli Lilly and Company
 Patent Division
 P.O. Box 6288
 Indianapolis, Indiana 46206-6288

April 2, 2003

RECEIVED

APR 10 2003

OFFICE OF PETITIONS



CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Susan Buis

Type or print name of person signing certification

Susan Buis April 2, 2003

Signature

Date

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,690,951

Patentees : David B. Anderson, et al. Attn: Box Patent Ext.

Assignee : Eli Lilly and Company

Issue Date : September 1, 1987

Docket No. : X-5683B

LETTER OF TRANSMITTAL OF AMENDMENT AND SUPPLEMENT TO APPLICATION
FOR EXTENSION OF PATENT TERM

Assistant Commissioner for Patents

Arlington, VA 22202

Sir:

Transmitted herewith for filing is a supplement to an application for extension of term of U.S. Patent No. 4,690,951 and a duplicate thereof, certified as such.

The original Application for Extension of Patent Term was filed February 18, 2000. Upon further review of the Request for Extension of Patent Term, on or about March 28, 2003, amendments and supplementation were necessary and are addressed by the enclosed Amendment and Supplement.

Please charge the filing fee of \$1,120 to deposit account No. 05-0840 in the name of Eli Lilly and Company. An original and two copies of this paper are enclosed. The Assistant Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to account No. 05-0840.

The Amendment and Supplement to application for extension transmitted herewith has been executed by the undersigned agent of the owner of record of the subject patent.

ELI LILLY AND COMPANY

By: John C. Demeter
John C. Demeter
Attorney for Applicants
Registration No. 30,167
Phone: 317-276-3785

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

April 2, 2003

RECEIVED

APR 10 2003

OFFICE OF PETITIONS

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Susan Buis

Type or print name of person signing certification

Susan Buis

Signature

April 9, 2003

Date



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,690,951

Patentees : David B. Anderson, et al. Attn: Box Pat. Ext.
Assignee : Eli Lilly and Company
Issue Date : September 1, 1987
Docket No. : X-5683B

IN RE APPLICANT'S REQUEST FOR EXTENSION OF
PATENT TERM UNDER 35 U.S.C. 156
AMENDMENT AND SUPPLEMENT

Assistant Commissioner for Patents

Arlington, VA 22202

Sir:

Applicant respectfully requests that the above-captioned application for patent extension under 35 U.S.C. 156 be amended and supplemented in the following respects:

Background

1. Pursuant to Section 201(a) of the Drug Price Competition and Patent Term Restoration Act of 1984, Applicant requested an extension of the patent term of U.S. Patent No. 4,690,951, filed February 18, 2000.

2. Information was submitted in accordance with 35 U.S.C. 156(d) and 37 C.F.R. 1.710 et seq. and followed the numerical format set forth in 37 C.F.R. 1.740(a).

3. With reference to the numerical format set forth in 37 C.F.R. 1.740(a), under number (9), Applicant provided a statement that the patent claims a method of using the approved product, a showing which lists each applicable patent claim and the manner in which each applicable patent claim reads on the approved method of using the approved product.

RECEIVED

APR 10 2003

OFFICE OF PETITIONS

4. Applicant's extension application as originally filed stated claims 1-9 all read on an approved use for the approved product and provided a showing as to each of claims 1-9 and the manner in which each claim reads on the approved method of using the approved product.

Amendment

5. Applicant cancels that portion of the extension application stating each of claims 1, 2, 3, 4, 5 and 6 read on approved methods of using the approved product.

6. Applicant cancels that portion of the extension application providing a showing that each of claims 1, 2, 3, 4, 5 and 6 read on approved methods of using the approved product.

Supplemental Information

7. Applicant maintains that portion of the extension application stating claims 7, 8 and 9 each read on approved uses for the approved product.

8. Applicant maintains that portion of the extension application providing a showing as to each of claims 7, 8 and 9 reading on an approved method of using the approved product.

9. Each of claims 7, 8 and 9 is directed toward a method for improving leanness in domesticated animals.

10. At least at column 3, lines 56-59, in U.S. 4,690,951, Exhibit II, of the extension application, finishing swine are disclosed as within the defined scope of domesticated animals.

11. As shown on Label For Paylean, Exhibit I, in the extension application, one of the approved indications is increased carcass leanness in finishing swine.

12. Each of claims 7, 8 and 9 read on an approved method of using the approved product; increasing carcass leanness, an approved indication, in finishing swine, an approved domesticated animal species, by administering an effective amount of ractopamine hydrochloride, the approved product.

13. Upon further review of the extension application, on or about March 28, 2003, the cancelled portions of the extension application came to Applicant's attention.

14. Applicant has acted diligently after discovery that only claims 7, 8 and 9 of U.S. 4,690,951 read on the approved method of using the approved products.

15. Applicant states there was no deceptive intent on its part in the submission of the cancelled portions of the extension application. The cancelled portions of the extension application reflect an insufficient understanding of domesticated animal species that are ruminants and those that are not ruminants.

16. There was no harm to the public engendered by the cancelled portions of the extension application. The public was clearly provided notice that Applicant is seeking to extend the term of U.S. 4,690,951. Three of the originally asserted nine claims read on an approved method of using the approved product. It is only necessary that one claim read on an approved method of using an approved product.

17. Address all further correspondence to John C. Demeter, Eli Lilly and Company, Patent Division/ JCD - DC1104, Lilly Corporate Center, Indianapolis, Indiana 46285. Direct telephone calls to John C. Demeter, 317-276-3785.

18. The undersigned hereby certifies that this Amendment and Supplement to application for extension of patent term under 35 U.S.C. 156, is being submitted with a duplicate copy thereof.

19. As the undersigned agent of Eli Lilly and Company, the owner of record of U.S. Patent No. 4,690,951, I, John C. Demeter, declare that (1) I am a Patent Attorney authorized to practice before the Patent and Trademark Office and have general authority from Eli Lilly and Company to act on its behalf in patent matters; that (2) I have reviewed and understand the contents of this Amendment and Supplement and the application for extension of U.S. Patent No. 4,690,951 that (3) I believe the patent is subject to extension pursuant to 37 C.F.R. 1.710; that (4) I believe the length of extension claimed is fully justified under 35 U.S.C. 156 and applicable regulations; and that (5) I believe the patent for which this extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. 1.720.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent extension issuing thereon.

I hereby appoint as United States attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

<u>Attorney</u>	<u>Reg. No.</u>	<u>Attorney</u>	<u>Reg. No.</u>
Arvie J. Anderson	45,263	Paul J. Koivuniemi	31,533
Lynn D. Apelgren	45,341	Thomas LaGrandeur	51,026
Robert A. Armitage	27,417	Kirby Lee	47,744
Brian P. Barrett	39,597	Robert E. Lee	27,919
Michael T. Bates	34,121	James P. Leeds	35,241
Roger S. Benjamin	27,025	Nelsen L. Lentz	38,537
Gary M. Birch	48,881	Elizabeth A. McGraw	44,646
William R. Boudreaux	35,796	Douglas K. Norman	33,267
Steven P. Caltrider	36,467	Arleen Palmberg	40,422
Paul R. Cantrell	36,470	Thomas G. Plant	35,784
John Cleveland	50,697	Edward Prein	37,212
Charles E. Cohen	34,565	Grant E. Reed	41,264
Donald L. Corneglio	30,741	James J. Sales	33,773
Gregory A. Cox	47,504	Michael J. Sayles	32,295
Paula K. Davis	47,517	David M. Stemerick	40,187
John C. Demeter	30,167	Mark J. Stewart	43,936
Manisha A. Desai	43,585	Robert D. Titus	40,206
Paul J. Gaylo	36,808	Robert C. Tucker	45,165
Francis O. Ginah	44,712	Tina M. Tucker	47,145
Janet A. Gongola	48,436	MaCharri Vorndran-Jones	36,711
Amy E. Hamilton	33,894	Gilbert T. Voy	43,972
Danica Hostettler	51,820	Thomas D. Webster	39,872
Thomas E. Jackson	33,064	Lawrence T. Welch	29,487
Soonhee Jang	44,802	Alexander Wilson	45,782
Gerald P. Keleher	43,707	Mark A. Winter	53,782
James J. Kelley	41,888	MaryAnn Wiskerchen	45,511
		Dan L. Wood	48,613

retaining for myself to have in addition the power to revoke the power granted to all others listed above except that to Robert A. Armitage, Douglas K. Norman and Amy E. Hamilton.

ELI LILLY AND COMPANY

By: John C. Demeter
John C. Demeter
Attorney for Applicant
Registration No. 30,167
Phone: 317-276-3785

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

April 2, 2003